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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/425,742	10/22/1999	KARL THEODOR KRAEMER	DEAV1998/L071 US NP	9957		
22852	7590	11/26/2008	EXAMINER			
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				YU, GINA C		
ART UNIT		PAPER NUMBER				
1611						
MAIL DATE		DELIVERY MODE				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/425,742	KRAEMER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	GINA C. YU	1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 July 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23, 28, 29 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) 3, 9 and 41-44 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 2, 4-8, 10-23, 28, 29, 39 and 40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Receipt is acknowledged of response filed on July 31, 2008. Claims 1-23, 28, 29 and 39-44 are pending, of which claims 3, 9, 41-44 have been withdrawn from consideration. Claim rejection made under 35 U.S.C. § 103 (a) as indicated in the previous Office action dated April 2, 2008 is maintained for the reasons of record. The rejection statement of the previous Office action contained wrong U.S. Patent number for the Gaillard-Kelly reference: the correct patent number of the reference that had been cited through out the prosecution is U.S. 5411981 A, and the correction is accordingly made in this Office action.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 2, 4-8, 11-14, 22, 23, 28, 29, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaillard-Kelly (US 4946870) ("Gaillard") in view of Partain (US 4946870), Smith (US 5658559) ,and Cremophor RH 40 Technical Information (1997).**

The rejection is maintained for the reasons of record.

### ***Response to Arguments***

Applicant's arguments filed July 31, 2008 have been fully considered but they are not persuasive.

- 1. Addition of POE hydrogenated castor oil to an anti-aloepecia composition would have been obvious in view of the prior arts.**

Applicant argues that the cited art fails to teach or suggest the addition of a plasticizer. Applicant asserts that Cremophor teaches POE hydrogenated castor oil as a solvent and not as a plasticizer. Applicant also argues that the reference does not suggest any amount of POE hydrogenated castor oil that would function as a plasticizer and impart "suppleness and flexibility" to the composition.

In response, examiner notes that the claimed invention is directed to a composition and not a method of adding a plasticizer to a well known composition. Furthermore, in response to applicant's argument that POE hydrogenated castor oil is used as a plasticizer rather than a solvent, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, regardless of whether POE hydrogenated castor oil is employed as a plasticizer or solvent, the very same component exerts the same benefits to the composition. The "suppleness and flexibility" that is observed from the present invention would be also present a composition which employs POE hydrogenated castor oil which is employed as a solvent. While applicant asserts that the prior art does not suggest any amount of POE hydrogenated castor oil to function as a plasticizer, there is nothing in the record to indicate that the function of POE hydrogenated castor oil depends on its amount in a composition, nor is the weight amount of the component a claimed limitation in this case.

**2. There would have been a reasonable expectation of success in combining the teachings of the references.**

Applicant asserts that the cited art fails to suggest that compounds of formula (I) can be combined with the components of Partain, Smith, and the Cremophor pamphlet. Applicant asserts that there is no teaching or suggestion that the compounds of Gaillard-Kelly would be chemically compatible with the ingredients of the compositions disclosed in Partain or Smith. In response, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, the present rejection is not based on an “obvious to try” rationale. A *prima facie* case of obviousness has been established because the references provide sufficient motivation to combine the components for their specific known benefits to make a topical anti-alopecia and/or acne composition in similar type of vehicles, i.e., lotion. It is viewed that the chemical compatibility of the ingredients and how to formulate a stable composition would have been well within ordinary skill of the art.

Applicant asserts that the teachings of retinoic acid in Gaillard, Partain, Smith, and the Cremophor pamphlet do not address the issue of obviousness of combining the compounds of formula (I) with the other components of the claimed components. The argument is unconvincing because the fact that the references all teach retinoic acid

indicates that these references are analogous arts and thus combinable. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the prior arts are reasonably pertinent to the problem that applicant was concerned - to formulate an improved anti-acne and anti-alopecia topical composition. Gaillard teaches that the compounds of formula (I) is useful for treatment of acne and alopecia and to combine the active ingredient with retinoid or Minoxidil; Partain teaches to formulate a controlled release composition for treatment of acne and alopecia with retinoic acid and Minoxidil. The compounds of formula (I) are not vitamins or essential oils, but Gaillard and Partain teaches using retinoic acid, which the Cremophor pamphlet explicitly teaches is the ideal hydrophobic pharmaceutical for which POE hydrogenated castor oil works. The cited references were relevant to one another and to the present invention and available to one of ordinary skill in the art at the time of the present invention. Combining the teachings of the reference and add POE hydrogenated castor oil to the composition of Gaillard/Partain would have been obvious to a skilled artisan.

### **3. Claims 15, 18, 19, 20, and 21**

Applicant's arguments rely upon the presupposition that rejection made on the claim 1, the base claims of claims 15, 18, 19, 20, and 21 are invalid. Since examiner

Art Unit: 1611

maintains the rejection for reasons above, applicant's arguments here are viewed unpersuasive.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1611

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/  
Primary Examiner, Art Unit 1611